5. 510(k) Summary

JUL 2 6 2013

Device Trade Name:	Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins
Manufacturer:	Gebr. Brasseler GmbH & Co. KG
Contact:	Gebr. Brasseler GmbH & Co. KG Trophagener Weg 25 • 32657 Lemgo Postfach 160 • 32631 Lemgo Germany Phone: +49 5261 701 467 Fax: +49 5261 701 96467
Prepared by:	Musculoskeletal Clinical Regulatory Advisers, LLC 1331 H Street NW, 12th Floor Washington, DC 20005 Phone: (202) 552-5800 Fax: (202) 552-5798
Date Prepared:	April 30, 2013
Classifications:	21 CFR 888.3040, Smooth or threaded metallic bone fixation fasteners.
Common Name:	Screw, Fixation Bone Pin, Fixation, Smooth or Threaded
Class:	II
Product Codes:	HWC, HTY and JDW

Indications For Use:
The Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Device Description:
Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws are available in several diameters and lengths, in both threaded and non-threaded designs with a variety of point geometries.

Substantial Equivalence
The Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws are substantially equivalent to the following devices: SMT Schilling Metalltechnik GmbH Orthopaedic Fixation Pins and Wires, Kirschner, Guide Wires (K100736); DePuy Inc.

Sterile Kirschner Wires and Steinmann Pins (K960385); OrthoPro, LLC OrthoPro Steinman Pins and Kirschner Wires (K070555); Treu-Instrumente GmbH Treu Bone Fixation Screws and Pins (K083912); with respect to indications, materials, and technological characteristics.

Preclinical Testing:
The Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws have similar physical dimensions, materials and technological characteristics as the identified predicate devices, and the substantial equivalence rationale is based on comparisons of these parameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 26, 2013

Gebr. Brasseler GmbH & Company KG
% Musculoskeletal Clinical Regulatory Advisers, LLC
Ms. Erela Dana
Associate, Regulatory Affairs
1331 H Street Northwest 12th Floor
Washington, District of Columbia 20005

Re: K131264
Trade/Device Name: Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, HTY, JDW
Dated: July 3, 2013
Received: July 5, 2013

Dear Ms. Dana:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K131264

Device Name: Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws

The Komet Medical Kirschner Wires, Steinmann Pins and Guide Pins and Screws are indicated for use in fixation of bone fractures, for bone reconstructions, as guide pins for insertion of other implants or implantation through the skin so that traction may be applied to the skeletal system.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Lori A. Wiggins

Division of Orthopedic Devices